



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments on the Maternal Immunizations Working Group's Draft Report and Draft Recommendations for Reducing Patient and Provider Barriers to Maternal Immunizations for Consideration by the National Vaccine Advisory Committee.

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, National Vaccine Program Office.

**ACTION:** Notice.

**SUMMARY:** The National Vaccine Advisory Committee (NVAC) was established in 1987 to comply with Title XXI of the Public Health Service Act (Pub. L. 99-660) (§2105) ([42 U.S. Code 300aa-5 \(PDF - 78 KB\)](#)). Its purpose is to advise and make recommendations to the Director of the National Vaccine Program on matters related to program responsibilities. The Assistant Secretary for Health (ASH) has been designated by the Secretary of Health and Human Services (HHS) as the Director of the National Vaccine Program. The National Vaccine Program Office (NVPO) is located within the Office of the Assistant Secretary for Health (OASH), Office of the Secretary, U.S. Department of Health and Human Services (HHS). NVPO provides leadership and fosters collaboration among the various federal agencies involved in vaccine and immunization activities. The NVPO also supports the National Vaccine Advisory Committee

(NVAC). The NVAC advises and makes recommendations to the ASH in his capacity as the Director of National Vaccine Program on matters related to vaccine program responsibilities.

In June 2012, the NVAC accepted a charge from the ASH to review the current state of maternal immunization and existing best practices and identify programmatic barriers to the implementation of current recommendations related to maternal immunization. The NVAC formed the Maternal Immunizations Working Group in August 2012 to address this charge.

Through a series of teleconferences, electronic communications, and public discussions during NVAC meetings, the working group developed a number of draft recommendations for consideration by the NVAC. The NVAC draft report details the background and rationale for each of these recommendations and provides input on how the ASH might support HHS activities in these areas. The draft report and draft recommendations from the working group will inform NVAC deliberations as the NVAC finalizes their recommendations for transmittal to the ASH.

NVPO is soliciting public comment on the draft report and draft recommendations from a variety of stakeholders, including the general public, for consideration by the NVAC as they develop their final recommendations to the ASH. It is anticipated that the draft report and draft recommendations, as revised with consideration given to public comment and stakeholder input, will be presented to the NVAC for adoption in June 2014 at the quarterly NVAC meeting.

**DATES:** Comments for consideration by the NVAC should be received no later than 5:00 p.m. EDT on [INSERT DATE 30 DAYS FOLLOWING DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:**

(1) The draft report and draft recommendations are available on the web at

<http://www.hhs.gov/nvpo/nvac/index.html>

(2) Electronic responses are preferred and may be addressed to: Jennifer.Gordon@hhs.gov.

(3) Written responses should be addressed to:

National Vaccine Program Office,

U.S. Department of Health and Human Services,

200 Independence Avenue, SW, Room 733G,

Washington, D.C. 20201.

Attn: HHS Maternal Immunizations c/o Dr. Jennifer Gordon

**FOR FURTHER INFORMATION CONTACT:**

Jennifer Gordon, Ph.D., National Vaccine Program Office, Office of the Assistant Secretary for Health, Department of Health and Human Services; telephone (202) 260-6619; fax (202) 260-1165; email: Jennifer.Gordon@hhs.gov.

**SUPPLEMENTARY INFORMATION:**

I. Background

Pregnant women and their infants are at increased risk for serious complications due to vaccine-preventable diseases. For example, during the 2009 H1N1 influenza pandemic, pregnant women accounted for five percent of all reported H1N1-related deaths and were 7.2 times more likely to be hospitalized than non-pregnant women. Infants too young to be vaccinated are also vulnerable to severe outcomes and death due to influenza and pertussis disease. Maternal immunization is an important strategy to protect both pregnant women and their young infants from vaccine-preventable disease, and both the Advisory Committee for Immunization Practices and the American College of Obstetricians and Gynecologists recommend that all pregnant women receive immunizations against influenza and pertussis disease during every pregnancy. However, despite evidence to support clear health benefits of maternal immunization for pregnant women and infant, immunization coverage in pregnant women remains low. In addition, many pregnant women reported that their provider did not recommend that they receive vaccines, indicating ongoing missed opportunities during healthcare interactions. Therefore, it is critical to understand the barriers that both prevent pregnant women from receiving recommended vaccinations and those that prevent obstetrical care providers from recommending and administering vaccines within their practices. Doing so will help to advance maternal immunization efforts and increase coverage to maximize the number of pregnant women and young infants that can benefit from these strategies.

Through their analysis and discussion, the NVAC identified five major areas of opportunity:

1. Enhancing communication to address the safety and effectiveness of all currently recommended immunizations during pregnancy;

2. Maximizing obstetric provider recommendation and administration of recommended maternal immunizations;
3. Focusing efforts to improve financing for immunization services during pregnancy and postpartum;
4. Supporting efforts to increase the use of electronic health records (EHRs) and Immunization Information Systems (IISs) among obstetrical care providers; and
5. Recognizing and addressing current vaccine liability law barriers to optimize investigations and uptake of recommended and future vaccines during pregnancy.

Within each area the NVAC report details key recommendations to overcoming challenges in these areas.

## II. Request for Comment

NVPO, on behalf of the NVAC Maternal Immunizations Working Group, requests input on the draft report and draft recommendations. In addition to general comments on the draft report and draft recommendations, NVPO is seeking input on efforts or barriers to maternal immunizations not represented in the report where HHS efforts could advance maternal immunization efforts.

Please limit your comments to six (6) pages.

## III. Potential Responders

HHS invites input from a broad range of stakeholders including individuals and organizations that have interests in maternal immunization efforts and the role of HHS in advancing those efforts.

Examples of potential responders include, but are not limited to, the following:

- general public;
- advocacy groups, non-profit organizations, and public interest organizations;
- academics, professional societies, and healthcare organizations;
- public health officials and immunization program managers;
- obstetrical care provider groups including all physician and non-physician providers that administer healthcare services to pregnant women, including pharmacists; and
- representatives from the private sector.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. Anonymous submissions will not be considered. Written submissions should not exceed six (6) pages. Please do not send proprietary, commercial, financial, business, confidential, trade secret, or personal information.

**Dated:** March 13, 2014.

Bruce Gellin,

Deputy Assistant Secretary for Health,

Director, National Vaccine Program Office,

Executive Secretary, National Vaccine Advisory Committee.

